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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/502,431

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Curtis C. Harris

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KLARQUIST SPARKMAN, LLP
121 S.W. SALMON STREET
SUITE #1600
PORTLAND, OR 97204-2988

EXAMINER

HALVORSON, MARK

ART UNIT

PAPER NUMBER

1642

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/17/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/502,431

Applicant(s)

HARRIS ET AL.

Examiner

Mark Halvorson

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 3-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☒ Claim(s) 2 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 7/22/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☒ Other: sequence search.

DETAILED ACTION

Claims 1-43 are pending.

Election/Restrictions

Applicant's election with traverse of Group 1 in the reply filed on Dec 4, 2006 is acknowledged. The traversal is on the ground(s) that the special technical feature of claim 1, as amended, does define a contribution over the prior art for each of the claimed inventions in the group of inventions. This is not found persuasive because the special technical feature of claim 1, as amended, does not define a contribution over the prior art.

Previously the special technical feature linking Groups 1-14 was that they all related to a tumor suppressor protein, p28ING5, comprising amino acid residues 1-13 of SEQ ID NO:2. Applicant has amended claim 1 to a sequence comprising amino acid residues 1-13 and 227-240 of SEQ ID NO:2. However, Azimzai et al (U.S. Patent Application Publication 2006/0127894, published Jun 15, 2006, filing date Aug 8, 2002, priority date Sep 7, 2001) disclose a protein identical to SEQ ID NO:2 of the present invention except for amino acid proline at position 170 instead of serine. (see sequence search). Thus, Azimzai et al protein anticipates the instant applicant's p28ING5 protein comprising amino acids residues 1-13 and 227-240 of SEQ ID NO:2.

Thus, the different groups in the present application do not contain a single inventive concept and puts a serious search burden on the Examiner.

Because newly cited art was necessitated by amendment the requirement is still deemed proper and is therefore made FINAL.

Claims 3-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1 and 2 are examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 is drawn to a genus of purified p28ING5 tumor suppressor proteins having a sequence comprising amino acid residues 1-13 and 227-240 of SEQ ID NO: 2, or a sequence having one or more conservative substitutions thereof.

The specification discloses only one purified p28ING5 tumor suppressor protein, the protein of SEQ ID NO:2.

The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that “[a] written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials.” *Id.* At 1567, 43 USPQ2d at 1405. The court concluded that “naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.” *Id.*

The Federal Circuit has recently clarified that a molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that the written description requirement can be met by “show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristicsi.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.” *Id.* At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

Thus, the instant specification may provide an adequate written description of the genus of p28ING5 tumor suppressor proteins, per Lilly by structurally describing a representative number of p28ING5 tumor suppressor proteins that function as claimed or by describing structural features common to the members of the genus, which

features constitute a substantial portion of the genus. Alternatively, per Enzo, the specification can show that the claimed invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.

In this case, the specification does not describe the genus of binding compounds or the genus of p28ING5 tumor suppressor proteins in a manner that satisfies either the Lilly or Enzo standards. There are insufficient structural features common to all members of the genus of polypeptide antagonists. The genus of p28ING5 tumor suppressor proteins encompasses any polypeptide having a conservative amino acid substitution at any position of SEQ ID NO:2. The protein of SEQ ID NO:2 has 240 amino acids. Most of these amino acids can be substituted by up to three other amino acids. This encompasses a multitude of p28ING5 tumor suppressor proteins, only one of which is identified in the instant specification. One species of p28ING5 tumor suppressor protein, does not sufficiently describe the genus of p28ING5 tumor suppressor proteins and does not meet the standard set forth in Lilly.

The instant specification may also provide an adequate written description of the genus of polypeptide antagonists if the specification can show that the claimed invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. The specification discloses only one species of p28ING5 tumor suppressor protein.

Art Unit: 1642

Thus, the specification does not describe sufficient structural characteristics that correlate with the ability of the genus of p28ING5 tumor suppressor proteins to function as contemplated by the specification and for the reasons set forth above do not meet the standards set forth by Enzo.

Thus, the specification does not provide an adequate written description of the genus of genus of p28ING5 tumor suppressor proteins of claim 1 that is required to practice the claimed invention.

In addition, the limitation amino acid residues 227-240 of SEQ ID NO:4 is NEW MATTER. The specification, as filed, does not describe the amino acid fragment 227-240 of SEQ ID NO:2..

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Azimzai et al (U.S. Patent Application Publication, published Jun 15, 2006, filing date Aug 8, 2002, priority date Sep 7, 2001).

Art Unit: 1642

Claim 1 is drawn to a purified p28ING5 tumor suppressor protein having a sequence comprising amino acid residues 1-13 and 227-240 of SEQ ID NO: 2, or a sequence having one or more conservative substitutions thereof.

Azimzai et al disclose a polypeptide having an amino acid sequence of SEQ ID NO:16 that is identical except for a proline at position 170 instead of a serine. Thus, Azimzai et al's peptide comprises amino acid residues 1-13 and 227-240 of SEQ ID NO: 2 of the instant application.

Summary

No claims allowed. Claim 2 is objected to as being dependent on a rejected claim. Claim 2 would be allowable if rewritten in independent form. The closest prior art is Azimzai et al that discloses a protein identical to SEQ ID NO:2 of the present invention except for amino acid proline at position 170 instead of serine.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Halvorson, PhD whose telephone number is (571) 272-6539. The examiner can normally be reached on Monday through Friday from 8:30am to 5 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley, can be reached at (571) 272-0898. The fax phone number for this Art Unit is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

Art Unit: 1642

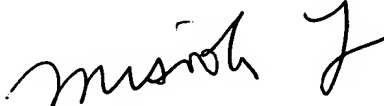
published applications may be obtained from either Private PAIR or Public PAIR.

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Business Center (EBC) at 866-217-9197 (toll-free).

Mark Halvorson, PhD
Patent Examiner
571-272-6539


MISOOK YU
PRIMARY EXAMINER